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13 UNITED STATES DISTRICT COURT
14 NORTHERN DISTRICT OF CALIFORNIA
15 SAN FRANCISCO DIVISION

16 In re CONNETICS SECURITIES
LITIGATION

Case No. C 07-02940 SI

CLASS ACTION

18 **LEAD PLAINTIFF'S OPPOSITION
19 TO REQUEST FOR JUDICIAL
NOTICE BY DEFENDANTS
20 CONNETICS CORP., JOHN L.
HIGGINS, LINCOLN KROCHMAL,
C. GREGORY VONTZ, AND
21 THOMAS G. WIGGANS**

22 Date: August 15, 2008
23 Time: 9:00 a.m.
Courtroom: 10
Judge: Hon. Susan Illston

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1 **I. INTRODUCTION**

2 Lead Plaintiff Teachers' Retirement System of Oklahoma ("Lead Plaintiff") opposes
 3 defendants' Request for Judicial Notice ("RJN") as contrary to Fed. R. Evid. 201 and law
 4 governing motions to dismiss under Fed. R. Civ. P. 12(b)(6). In connection with their Motions
 5 to Dismiss the Second Amended Consolidated Class Action Complaint, defendants Connnetics
 6 Corp. ("Connnetics" or the "Company"), John L. Higgins, Lincoln Krochmal, C. Gregory Vontz,
 7 and Thomas G. Wiggans (collectively "defendants") ask the Court to take judicial notice of
 8 extraneous material consisting of 52 documents, totaling over 800 pages.

9 Lead Plaintiff does not oppose consideration of certain public documents, the contents of
 10 which are proper subjects for judicial notice of the existence of statements therein. Rather, Lead
 11 Plaintiff opposes defendants' request that the Court take judicial notice of Exhibits 6, 7, 8, 10,
 12 12, 13, 31-43, and 48 for the truth of factual matters asserted therein that are disputed by Lead
 13 Plaintiff. *See infra* § II.C. For instance, defendants seek judicial notice of the purported "fact"
 14 that the Company's restatement of financial results was not their fault but, rather, was the result
 15 of "inaccurate and inconsistent inventory level reports provided by [Connnetics'] three main
 16 wholesale customers." *See infra* § II.C.1. Defendants' far-fetched notion of simultaneous
 17 mistaken reports from three separate distributors is neither a "fact" nor is it even reasonable, let
 18 alone undisputed, in light of Lead Plaintiff's well-pleaded allegations.

19 Similarly, defendants seek judicial notice of Exhibit 48 for the purported fact that the
 20 Tg.AC mouse study "is not always a reliable indicator of risk to humans and is known to have a
 21 high rate of 'false positives.'" Connnetics MTD at 24. This "fact" is not at all true. *See infra* §
 22 II.C.2. To the contrary, Exhibit 48 states "the transgenic models had a high percentage of correct
 23 calls. . . . Overall, the transgenic models performed well . . ." Ex. 48 at 3. Moreover, Exhibit 48
 24 does not establish – indeed, it does not even support – the contention that the Tg.AC mouse
 25 studies are "known to have a high rate of 'false positives.'" *See infra* § II.C.2.

26 Disputed facts such as these are not proper for judicial notice, regardless of whether they
 27 are found in a public document such as Connnetics' filings with the Securities and Exchange
 28 Commission ("SEC"). *See infra* § II.A. and § II.B.

1 Lead Plaintiff also opposes judicial notice of Exhibits 49-50, which appear to be created
 2 by defendants' counsel and which are misleading portrayals of what they purport to represent.
 3 See *infra* § II.D. Such exhibits are improper material for judicial notice. See, e.g., *In re CV*
 4 *Therapeutics Inc. Sec. Litig.*, No. C 03-03709-SI, 2004 WL 1753251, at *12 (N.D. Cal. Aug. 5,
 5 2004) (refusing to take judicial notice of charts prepared by defense counsel, "since the Court is
 6 capable of synthesizing information").

7 In relying upon these exhibits, defendants attempt to resolve a number of factual disputes
 8 prior to discovery and development of the record, which is inappropriate at this early stage of
 9 litigation. Lead Plaintiff is mindful of the Court's prior ruling that "in a securities action a court
 10 may also consider documents that the defendant has attached to its motion to dismiss either as
 11 exhibits or accompanied by a request for judicial notice." January 29, 2008 Order (the "1/29
 12 Order" [Doc. No. 83]) at 6 (citing *Weiner v. Klais and Co., Inc.*, 108 F.3d 86, 88 (6th Cir. 1997)).
 13 Lead Plaintiff respectfully submits, however, that defendants' current request that the Court take
 14 judicial notice of anything and everything is contrary to law. By judicially noticing a fact, that
 15 fact is deemed irrefutable for the purposes of the litigation. See Fed. R. Evid. 201 ("the court
 16 shall instruct the jury to accept as conclusive any fact judicially noticed"). The truth of
 17 defendants' own statements or assertions by others in documents are not conclusive.

18 **II. ARGUMENT**

19 **A. Legal Standards**

20 At the motion to dismiss stage, "courts must consider the complaint in its entirety, as well
 21 as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in
 22 particular, documents incorporated into the complaint by reference, and matters of which a court
 23 may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499, 2509
 24 (2007). There are only two exceptions to the rule that the Court must consider material only
 25 within the four corners of a complaint. *Id.*; *Lee v. City of Los Angeles*, 250 F.3d 668, 688-89 (9th
 26 Cir. 2001).

27 First, a court may consider documents properly submitted as part of the complaint or,
 28 under the "incorporation by reference" doctrine, documents upon which the complaint

1 necessarily relies and the authenticity of which is not disputed. *Lee*, 250 F.3d at 688-90; *see*
 2 *Cooper v. Pickett*, 137 F.3d 616, 623 (9th Cir. 1998) (“a court ruling on a motion to dismiss may
 3 consider the full texts of documents which the complaint quotes only in part”). The purpose for
 4 this exception is to allow the court to assess the complaint’s allegations in context.

5 Second, a court may take judicial notice of facts that are: (1) “matters of public record,”
 6 *Lee*, 250 F.3d at 689; or (2) “capable of accurate and ready determination by resort to sources
 7 whose accuracy cannot reasonably be questioned,” Fed. R. Evid. 201(b). But, “this is a narrow
 8 exception It is not intended to grant litigants license to ignore the distinction between
 9 motions to dismiss and motions for summary judgment.” *In re Immune Response Sec. Litig.*, 375
 10 F. Supp. 2d 983, 995 (S.D. Cal. 2005) (citation omitted). The Court should not consider exhibits
 11 to a motion to dismiss where “Defendants offer the documents as evidence that Defendants did
 12 not commit securities violation[s].” *Id.*

13 “A judicially noticed fact must be one not subject to reasonable dispute” Fed. R.
 14 Evid. 201(b). The Ninth Circuit holds that a district court may judicially notice “undisputed
 15 matters of public record” but *not* “disputed facts stated in public records.” *Lee*, 250 F.3d at 688-
 16 90. Thus, while a court may take judicial notice of the existence of a document and the existence
 17 of the statements contained in the document, it may not take judicial notice of the truth of the
 18 matters asserted in that document to resolve disputed factual matters. *See, e.g., id.; Shurkin v.*
 19 *Golden State Vintners, Inc.*, 471 F. Supp. 2d 998, 1011 (N.D. Cal. 2006) (“the Court takes
 20 judicial notice of these documents, ***not for the truth of the statements contained therein***, but for
 21 the fact that these documents that were publicly-filed and for the fact that the statements made
 22 therein were made to the public on the dates specified”) (emphasis added); *In re Northpoint*
 23 *Comm’ns Group, Inc., Sec. Litig.*, 221 F. Supp. 2d 1090, 1095 (N.D. Cal. 2002) (refusing to
 24 consider filings with the SEC that defendants wanted judicially noticed because they contained
 25 disputed facts); *United States v. S. Cal. Edison Co.*, 300 F. Supp. 2d 964, 975 (E.D. Cal. 2004)
 26 (“While the court may take judicial notice of the general meaning of words, phrases, and legal
 27 expressions, documents are judicially noticeable only for the purpose of determining what
 28 statements are contained therein, not to prove the truth of the contents or any party’s assertion of

1 what the contents mean.”).

2 **B. *Tellabs Did Not Change The***
 Law Governing Judicial Notice

3 The Supreme Court’s decision in *Tellabs*, 127 S. Ct. 2499, has not changed the law in this
 regard. *Id.* at 2509 (“courts must consider the complaint in its entirety, as well as other sources
 courts *ordinarily* examine when ruling on Rule 12(b)(6) motions to dismiss, in particular,
 documents incorporated into the complaint by reference, and matters of which a court may take
 judicial notice”) (emphasis added). In articulating a standard for assessing scienter, the Supreme
 Court recognized that on a motion to dismiss the district court is limited to inferences drawn
 from the plaintiff’s complaint. “A complaint will survive, we hold, only if a reasonable person
 would deem the inference of scienter cogent and at least as compelling as any opposing inference
 one could draw from the facts alleged.” *Id.* at 2510 (emphasis added). “Defendants’ arguments
 [outside the four corners of the complaint] are inappropriate at this stage of the litigation.
 Opposing inferences may only be based on the allegations of the Complaint, which must be
 taken as true, and other documents properly before the court on a motion to dismiss.” *In re*
 Scottish Re Group Sec. Litig., 524 F. Supp. 2d 370, 390 (S.D.N.Y. 2007). *See also In re Top*
 Tankers, Inc. Sec. Litig., 528 F. Supp. 2d 408, 418 (S.D.N.Y. 2007) (on motion to dismiss,
 “*Tellabs . . . notwithstanding, it remains the case that at this point in the lawsuit, the court may*
 not ‘weigh the evidence that might be presented at trial,’ but must instead limit itself to
 considering all of the facts alleged in the complaint, taken collectively.”) (citations omitted). It
 remains “the jury’s authority to assess the credibility of witnesses, resolve any genuine issues of
 fact, and make the ultimate determination whether [defendants] acted with scienter.” *Tellabs*,
 127 S. Ct. at 2513.

23 Now, as before *Tellabs*, the Complaint’s allegations are accepted as true and the Court
 24 may only consider matters outside the pleadings if they fit within this narrow exception. *See*
 25 *Lee*, 250 F.3d at 688-90.

1 **C. It Is Improper To Take Judicial Notice Of Documents**
 2 **For The Truth Of Disputed Facts Asserted Therein**

3 Defendants seek judicial notice of publicly available documents for the purpose of
 4 contending that statements set forth therein are true facts that somehow negate Lead Plaintiff's
 5 allegations. This is improper. *See, e.g., Perretta v. Prometheus Dev. Co.*, No. C-05-02987-
 6 WHA, 2006 U.S. Dist. LEXIS 10108, at *7-8 (N.D. Cal. Feb. 24, 2006) ("Such public
 7 documents . . . are judicially noticeable only for the purpose of determining what statements are
 8 contained therein, not to prove the truth of the contents"). The Court should not accept as true
 9 defendants' own disputed factual assertions and self-serving version of events simply because
 10 these statements appear in publicly available documents – some written by defendants.

11 **1. SEC Filings Referenced In The Complaint**

12 Exhibits 6, 7, 8, 10, 12, and 13 are Company-prepared SEC filings referenced in the
 13 Complaint. The Court may consider these documents for the purpose of determining what the
 14 documents state. It is improper, however, to judicially notice the SEC filings for the truth of the
 15 statements contained therein because the accuracy of such statements is disputed. *See, e.g.*
 16 *Northpoint*, 221 F. Supp. 2d at 1095 (refusing to consider SEC filings that defendants wanted
 17 judicially noticed because they contained disputed facts); *In re Adaptive Broadband Sec. Litig.*,
 18 No. C 01-1092-SC, 2002 WL 989478, at *20 (N.D. Cal. Apr. 2, 2002) (taking judicial notice that
 19 statements were made in a Form 10-K referenced in the complaint but not taking judicial notice
 20 of the truth of the statements).¹

21 **Exhibit 7**

22 Defendants request that the Court take judicial notice of Connetics' amended Form 10-K
 23 for 2005, which was filed by the Company with the SEC on July 25, 2006. Exhibit 7 was signed
 24

25 ¹ Lead Plaintiff is aware that this Court has previously stated that it does not "restrict its taking
 26 of judicial notice [as to the truth of their contents]." *See CV Therapeutics*, 2004 WL 1753251, at
 27 *12. Unlike here, however, plaintiffs in *CV Therapeutics* only broadly opposed judicial notice
 28 with boilerplate objections that the facts were disputed. *See* Opposition Brief, *CV Therapeutics*,
 Case No. 03-03709 [Docket No. 75]. Here, in contrast, Lead Plaintiff sets forth specific
 examples of the improper use of the exhibits by defendants and why the specific contents of the
 documents are disputed. The Ninth Circuit's holding in *Lee* applies. *Lee*, 250 F.3d at 688-89.

1 by defendants Higgins and Wiggins, and contains Connetics' restated financial results.
 2 Defendants offer Exhibit 7 for the purpose of providing defendants' explanation of why the
 3 Company had to restate its financial results:

4 Connetics' reserve estimates were impacted by inaccurate and inconsistent
 5 inventory level reports provided by its three main wholesale customers. Ex. 7, at
 6 31, 43-44 (Form 10-K/A). Once Connetics began to receive accurate reports, it
 7 was able to conclude that its product inventory at these wholesalers was higher
 than previously estimated, and accordingly took steps to increase its reserves. *See id.*

8 Connetics MTD at 13, fn. 14. This is defendants' own construct, set forth in a document they
 9 authored and signed. Defendants offer Exhibit 7 for a wholly improper purpose, to have the
 10 Court accept as a true facts that may "reasonably be questioned." Fed. R. Evid. 201(b).

11 Defendants' request for judicial notice of their faulty reports "explanation" is contrary to
 12 the well-pleaded allegations. The Complaint extensively details former employees' accounts of
 13 how the defendants purposefully shipped excess product to Connetics' distributors at the end of
 14 quarters – far beyond the amount of product being used by consumers. ¶¶166-174. Moreover,
 15 defendants repeatedly assured investors that the Company closely monitored its distributors'
 16 inventory levels "using a combination of techniques." ¶158. Connetics did so by "tracking the
 17 prescriptions filled for our products at the pharmacy level" based on information provided by
 18 independent third parties. ¶¶158-159. Moreover, defendants have admitted Connetics had to
 19 restate not as a result of faulty reports but because they calculated reserves without taking into
 20 account the fact that distributors who returned expired product oftentimes received far in excess
 21 of the initial sale price that the distributor paid:

22 *[W]e calculated the value of the estimated units to be returned using the
 23 original sales price without taking into account price increases that were
 24 implemented between the date of sale through the period of the accrual.* We
 25 permit wholesalers to return expired or expiring product for a credit at the then-
 current sales price less 5%, so the initial sales price may not fully capture our
 26 liability for future returns. As a result of our evaluation, we determined that our
 accrual for product returns had been understated and concluded that the impact of
 the errors required us to restate our financial statements for prior years.

27 ¶188. Accordingly, the well-pleaded facts demonstrate the falsity of defendants' explanation for
 28 why they had to restate Connetics' prior financial results. Accordingly, the Court cannot take

1 judicial notice of this faulty reports explanation for the truth of the matter asserted.

2 Furthermore, defendants' faulty reports "explanation" for the restatement is contrary to
 3 Exhibit 7 itself. As set forth in the Complaint at ¶192, the Company's amended 2005 Form 10-K
 4 includes an explanation describing the basis for the Company issuing restated financial results –
 5 and this explanation nowhere references inaccurate inventory reports. *See also* Declaration of
 6 David Stickney in Support of Opposition to Request for Judicial Notice ("Stickney Decl.") at Ex.
 7 A. Rather, the explanation attributes the restatement to facts known to the Company at the time
 8 the prior financial statements were prepared. *Id.* Elsewhere in the amended 2005 Form 10-K,
 9 the Company asserts it received some inaccurate inventory level reports – but the Form 10-K
 10 itself includes no connection between the purported inaccurate reports and the Company's need
 11 to restate prior financial results. *Id.* Indeed, it would be illogical to accept defendants'
 12 contention that the restatement was necessitated by inaccurate inventory reports because the
 13 accounting rules are clear that, under the circumstances here, a restatement is proper only where
 14 the company had the facts available to them at the time the financial statements were prepared.
 15 *See* ¶190. *See also In re WorldCom, Inc. Sec. Litig.*, 2005 U.S. Dist. LEXIS 2215 (S.D.N.Y.
 16 Feb. 17, 2005) ("Errors in financial statements result from mathematical mistakes, mistakes in
 17 the application of accounting principles, or oversight or misuse of facts that existed at the time
 18 the financial statements were prepared.").

19 To take judicial notice of defendants' self-serving "truth" simply because it is found in
 20 the Company's restatement is improper and would "allow officers and directors of corporations
 21 to exercise an unwarranted degree of control over whether they are sued, because they must
 22 agree to a restatement of the financial statements." *Aldridge v. A.T. Cross Corp.*, 284 F.3d 72,
 23 83 (1st Cir. 2002).

24 **Exhibit 8**

25 Exhibit 8 is Connetics' own Form 8-K filed with the SEC on or about May 24, 2002,
 26 attaching Connetics' own May 14, 2002 press release. This press release was issued by
 27 Connetics nearly two years prior to the beginning of the Class Period and prior to the Tg.AC
 28 mouse study. Defendants cite Exhibit 8 for the truth of the matters asserted in it, specifically:

1 “European clinical studies involving more than 700 patient had demonstrated that *Velac was*
 2 ***both safe and effective.***” Connetics MTD at 6. Defendants’ assertion that Velac was found to
 3 be “safe” is both misleading and disputed. Regardless of any European study, the FDA requires
 4 its own testing requirements be satisfied as a prerequisite for FDA approval. ¶73. Moreover,
 5 there is no indication that the purported European study even tested for carcinogenicity. If the
 6 purported study did not test for carcinogenicity, then the supposed findings are completely
 7 irrelevant and misleadingly cited by defendants. Moreover, defendants’ utilization of a press
 8 release preceding the findings of the Tg.AC study cannot alter the actual outcome of the FDA-
 9 mandated study that revealed Velac’s dangers and the certainty that the FDA would not approve
 10 the drug. Because the results of the purported studies from 2002 are not before the Court,
 11 defendants should not be allowed to build “a record” based on a single pre-Class Period press
 12 release that they wrote. If, at trial, defendants wish to argue that the FDA somehow failed to
 13 properly credit the European study over the alarming results of the Tg.AC study, such factual
 14 arguments can be addressed at that later stage based on a fully-developed record.

15 **Exhibits 6 and 10**

16 Similarly, defendants request judicial notice of Exhibits 6 and 10 for the purported fact
 17 that Phase III Clinical Testing had “excellent results” proving Velac was “safe and effective.”
 18 Connetics MTD at 8, 22. Phase III testing, however, did not assess Velac’s carcinogenicity.
 19 Accordingly, the Phase III test results could not establish Velac to be “safe” as far as
 20 carcinogenicity is concerned. Exhibits 6 and 10 are nothing more than defendants’ own self-
 21 serving, false and misleading characterizations of the Phase III test results. Indeed, Lead
 22 Plaintiff specifically asserts that these statements were false and misleading. See ¶¶250-251.
 23 Quite simply, defendants seek judicial notice of Exhibits 6 and 10 for an untrue fact – that the
 24 Phase III tests established Velac was safe and would be approved without successful preclinical
 25 studies.

26 **Exhibits 6 and 12**

27 Defendants seek judicial notice of Exhibits 6 and 12 for the purported fact that
 28 “Connetics incurred substantial time and expense to prepare and file the NDA,” suggesting that

1 the Company would not have spent such sums if defendants knew that Velac would not be
 2 approved. Connetics MTD at 10, 18-19. Defendants' argument is illogical because the
 3 individual defendants themselves expended nothing. *See Opp.* to MTD at page 14. Moreover,
 4 Exhibits 6 and 12 do not establish as a fact that "Connetics incurred substantial time and expense
 5 to prepare and file the NDA." Rather, Exhibits 6 and 12 merely state that Connetics made a
 6 ***contractually obligated*** "milestone payment" of \$3.5 million under the licensing agreement due
 7 to Yamanaouchi Europe B.V. in conjunction with submission of the Velac NDA. Lead Plaintiff
 8 objects to the Court taking judicial notice of these Exhibits to establish the fact that Connetics
 9 incurred "substantial time and expense" – from which defendants assert that defendants did not
 10 commit securities fraud. *See Immune Response*, 375 F. Supp. 2d at 995.

11 **Exhibit 13**

12 Similarly, defendants seek judicial notice of Exhibit 13 as purported evidence that
 13 Connetics "hir[ed] more than 60 new sales professionals in January 2005 as part of a sales force
 14 expansion" preparing for the launch of Velac. Connetics MTD at 10. Nothing in Exhibit 13
 15 suggests the hiring of new sales staff had anything to do with the Company's purported launch of
 16 Velac. If the Company hired 60 new sales people, it could have done so for any number of
 17 reasons, such as an attempt to rescue the lagging sales of its other drugs. Evoclin, for example,
 18 was the subject of a new "comprehensive sales and marketing program" at the time the Company
 19 hired the sales people. Ex. 13. The Court cannot take judicial notice of the purported fact that
 20 the Company hired new sales staff to sell Velac because that purported fact is simply not found
 21 anywhere in Exhibit 13 (or anywhere else for that matter) and is, in any event, irrelevant.
 22 Accordingly, the Court should not take judicial notice of this purported fact.

23 **2. Amended Complaint ¶56 And**
 24 **Exhibit 48: "Transgenic Mouse**
 25 **Models: Their Role In Carcinogen Identification"**

26 Defendants ask the Court to take judicial notice of the paper "*Transgenic Mouse Models:*
 27 *Their Role in Carcinogen Identification*" (Exhibit 48) and reference ¶56 of Lead Plaintiff's prior
 28 complaint for the purported fact: "The Tg.AC study, while faster than one conducted on a
 normal mouse, has ***significant limitations*** and does not always ***or reliably*** predict risks to

1 humans.” Connecitcs MTD at 7-8. Defendants also seek judicial notice of Exhibit 48 for the
 2 purported “fact that the Tg.AC study is not always a reliable indicator of risk to humans and is
 3 ***known to have a high rate of ‘false positives.’”*** Connecitcs MTD at 24. Neither ¶56, nor Exhibit
 4 48, supports defendants’ contention. Therefore, the Court should not take judicial notice of
 5 Exhibit 48 and should not consider ¶56 for the reasons defendants cite them. Indeed, in the
 6 Abstract for the paper “*Transgenic Mouse Models: Their Role in Carcinogen Identification*”
 7 (Exhibit 48), the authors explicitly state: “Although ***the transgenic models had a high***
 8 ***percentage of correct calls,*** they did mid miss a number of known or probable human
 9 carcinogens Overall, ***the transgenic models performed well*** *Id.* at 3. Accordingly,
 10 Exhibit 48 stands for the exact opposite conclusion than defendants assert.

11 Moreover, it is clear from a close reading that Exhibit 48 supports Lead Plaintiff’s
 12 position. The primary criticism of Tg.AC mouse studies in Exhibit 48 is that they sometimes
 13 result in a false negative. Ex. 48 at 3 (“they did mid miss a number of known or probable human
 14 carcinogens”). Here, Velac tested positive. Defendants essentially seek judicial notice that the
 15 results were meaningless. Exhibit 48 does not support defendants’ contention, and there is
 16 absolutely no truth to the statement that the Tg.AC mouse study “is ***known to have a high rate***
 17 ***of ‘false positives’”*** and therefore the Court cannot take judicial notice of this purported fact.

18 **3. FDA Labels And Notices (Exhibits 30-43)**

19 Defendants seek judicial notice of Exhibits 30-43 to establish the purported fact
 20 “defendants were ***aware*** that the FDA had approved other acne drugs that had tested positive in
 21 the Tg.AC model (such as, BenzaClin and Duac), requiring ***only*** post-approval Phase IV
 22 carcinogenicity testing” and not additional carcinogenicity testing prior to approval. Connecitcs
 23 MTD at 16. *See also id.* at 8.² Exhibits 30-43 are product labels and FDA letters for various
 24 drugs (BenzaClin, Duac, Differin, Retin-A, Protopic, Aldara, and Clobex). While the Court may
 25 take judicial notice of publicly available FDA documents “whose accuracy cannot reasonably be
 26 questioned,” Fed. R. Evid. 201(b), the Court may not take judicial notice of these Exhibits for the

27
 28 ² Lead Plaintiff notes that Exhibits 42-43 are not cited in defendants’ MTD, although the exhibits are included in the RJN.

1 purposes defendants offer them. The Court cannot take judicial notice of defendants' *ipse dixit*
2 assertions that these drugs are somehow *similar* to Velac. See Connexis MTD at 8, 16. Nor can
3 the Court take judicial notice that defendants were *aware* of this extraneous material prior to the
4 litigation. Finally, the Court cannot take judicial notice of facts not supported by the documents,
5 including the unsubstantiated fact that the FDA approved any of these drugs without *first*
6 *requiring additional animal testing to establish safety.*

7 Whether or not the drugs cited by defendants had *similar* safety concerns as Velac, is not
8 at all discernable from the exhibits and this is a fact vigorously disputed by Lead Plaintiff. Velac
9 caused 56% of the mice in the Tg.AC mouse study to develop tumors. ¶92. Defendants put no
10 evidence before the Court to suggest any of these other drugs caused such a similarly high rate of
11 tumors in the Tg.AC mouse study. Without additional information about the severity of the
12 response in the Tg.AC mouse studies, the Court cannot take judicial notice of the "similarity" of
13 these drugs. Moreover, as set forth in great detail in the Complaint, statements found in one
14 product insert cannot be taken out of context and applied to another product to predict how the
15 FDA will respond because different drugs are not "similar" in the eyes of the FDA. ¶124.
16 Indeed, for instance, defendants' comparison of Velac to Differin's positive response in an "oral
17 study" (Ex. 34, at 4) is irrelevant because Velac was a topical treatment (not an oral treatment).
18 The point is that each drug works differently, and the FDA requires that each new drug (such as
19 Velac) independently demonstrate safety. ¶122. Whether any comparisons of drugs was (or is)
20 reasonable is properly the subject of expert testimony on a developed record. Accordingly, it is
21 improper to take judicial notice of the disputed "fact" that defendants were aware of other
22 products that had *similar* Tg.AC study results and levels of carcinogenicity that were approved
23 by the FDA.

24 Defendants adduce nothing to suggest that they were "aware" of, or relied upon, any of
25 the labels or drugs in Exhibits 30-43 when making their false statements. The fact that litigation
26 counsel found product labels when drafting their motions to dismiss says nothing about
27 defendants' state of mind during the Class Period. Conspicuously missing is any indication that
28 during the Class Period defendants relied upon these labels when analyzing Velac. Indeed,

1 defendants' contentions in this litigation are inconsistent with their damage-control statements
2 when announcing the FDA denied approval. Although now claiming that defendants were aware
3 of each of the drugs that received FDA approval despite "positive responses in carcinogenicity
4 studies" (Connetics MTD at 9), defendants only mentioned benzoyl peroxide as having "had a
5 positive finding" in the Tg.AC model and further stated that only one mouse in Velac's study
6 had a positive reaction. ¶120.

7 The Court should not take judicial notice of Exhibits 30-43 for the additional reason that
8 they are all irrelevant to addressing the Complaint's allegations. Lead Plaintiff pleads that as a
9 result of the positive Mouse Study results, defendants knew no later than June 2004 it was
10 extremely unlikely that Velac would be approved prior to the PDUFA date (June 25, 2005).
11 According to a recognized expert in use of the Tg.AC mouse study who served on the
12 Toxicology Panel ("CW5"), if more than 20% of the mice in a Tg.AC study develop tumors the
13 FDA requires further testing and will not approve that drug without first obtaining the results of
14 the additional testing. ¶¶96-97. Velac caused tumors in 56% of mice, thereby necessitating
15 lengthy additional testing. Similarly, according to a former Connetics Senior Manager of
16 Regulatory Affairs who handled Connetics' communications with the FDA ("CW6"), once
17 Connetics learned the results of the Tg.AC Mouse Study, there was nothing the Company could
18 do to prove Velac was safe other than a two year CARC study. ¶98. Because the Company, at
19 the very least, had to perform additional carcinogenicity testing in order to obtain FDA approval,
20 defendants knew approval by the PDUFA date was extremely unlikely. ¶99.

21 Exhibits 30-43 do not address whether the FDA would/might approve Velac prior to the
22 PDUFA date. Exhibits 30-43 do not address whether the FDA would/might approve any drug
23 that tested positively in a carcinogenicity test without first requiring additional animal testing
24 demonstrating the safety of the drug.

25 Defendants assert that Exhibits 31 and 33 are relevant to this issue because the FDA
26 approved these drugs after a positive Tg.AC test and required "**only post-approval** Phase IV
27 carcinogenicity testing and labeling." Connetics MTD at 16. Defendants' contention is not
28 supported by Exhibits 31 or 33. Both exhibits demonstrate that the FDA required post-approval

1 testing of the effects of the drug on UV-induced skin cancers. However, neither Exhibit 31 nor
 2 33 supports defendants' contention that the FDA approved these drugs without additional ***pre-***
 3 ***approval*** carcinogenicity testing demonstrating that the drug was not a carcinogen. Such
 4 additional testing is not disclosed in a product insert. *See ¶122.*

5 The eventual FDA approval of very few drugs that tested positively in Tg.AC mouse
 6 studies, assuming defendants were even aware of such approval, cannot have given defendants
 7 any basis to believe Velac would also be approved by the PDUFA date. The FDA requires
 8 carcinogenicity testing for a reason.

9 **D. Summary Exhibits 49 And 50 Created By**
 10 **Defendants Are Not Appropriate For Judicial Notice**

11 Exhibits 49 and 50 are documents prepared by defense counsel. These documents were
 12 not attached to the Complaint or referenced therein. Defendants cite these exhibits to challenge
 13 the accuracy of Lead Plaintiff's allegations and seek judicial notice of the disputed facts therein.
 14 These documents are not appropriate for the Court's consideration in ruling on a Rule 12(b)(6)
 15 motion and are improper material for judicial notice. *See, e.g., CV Therapeutics, 2004 WL*
 16 *1753251, at *12* (refusing to take judicial notice of charts prepared by defense counsel, "since
 17 the Court is capable of synthesizing information").

18 Exhibit 49 is a chart created by defense counsel which purports to set forth each of the
 19 Insider Defendants' stock sales as a percentage of their individual total holdings remaining "as of
 20 May 23, 2006, as reported in Connecitcs' 2006 proxy statement." Ex. 49, n.1. Relying on this
 21 document, defendants contend that each of the Insider Defendants sold only a small portion of
 22 his total holdings in Connecitcs, which defendants argue "refute[s] any inference of scienter."
 23 Connecitcs MTD at 31-32. Exhibit 49 is inherently misleading and the Court should not take
 24 judicial notice of it. In calculating the percentage of the defendants' total holdings sold during
 25 the Class Period, defendants improperly inflated the defendants' total holdings by including
 26 valueless stock options, *i.e.*, underwater options. By including underwater options in the total
 27 amount of stock retained by defendants, defendants distort downwards the percentage of their
 28 portfolios they sold to take advantage of fraud-induced inflation. Defendants have not disclosed,
 either publicly or before the Court, the amount of their unexercised options that were underwater

1 (and therefore worthless) that they have included as part of their personal, retained holdings
2 presented in this exhibit.

3 Defendants argue that whether underwater options are included in their calculations is
4 “legally irrelevant.” Connetics MTD at 31 n. 34. This dispute exemplifies why judicial notice is
5 inappropriate here because the information is based on a party’s subjective determination of the
6 applicable information. *See In re White Elec. Designs Corp. Sec. Litig.*, 416 F. Supp. 2d 754,
7 761 (D. Ariz. 2006) (declining to take judicial notice of a chart showing company’s stock prices
8 because there was a dispute whether the dates on the chart were accurate). Exhibit 49 is a
9 misleading document created by defense counsel that was not referred to, nor relied upon, in the
10 Complaint. As such, the validity of its contents is inherently suspect, thus making judicial notice
11 inappropriate. *See Cactus Corner, LLC v. U.S. Dep’t of Agric.*, 346 F. Supp. 2d 1075, 1100
12 (E.D. Cal. 2004) (declining to take judicial notice of the accuracy and validity of the contents of
13 a government report prepared solely for purposes of litigation). Accordingly, it would be
14 inappropriate for this Court to take judicial notice of Exhibit 49.

15 Exhibit 50 is a chart summarizing what defendants call “meaningful cautionary
16 language.” RJN at 9. The Court already determined that the language was not meaningfully
17 cautious. 1/29 Order at 13. Moreover, the chart is not a document that any investor saw.
18 Rather, it was created by defense counsel to make boilerplate “cautionary language” seem more
19 understandable than the form in which it actually appeared. Defendants imply that their reason
20 for presenting Exhibit 50 to the Court is merely to show the existence of cautionary statements.
21 *Id.* In their motion to dismiss, however, defendants rely on Exhibit 50 in an attempt to challenge
22 the accuracy of Lead Plaintiffs’ allegations that defendants’ disclosures misled the public.
23 Connetics MTD at 19. Consideration of such an argumentative document is improper at the
24 motion to dismiss stage. *See, e.g., In re Vantive Corp. Sec. Litig.*, 110 F. Supp. 2d 1209, 1213
25 (N.D. Cal. 2000) (refusing to consider defendants’ compilation of plaintiffs’ allegations and
26 defendants’ cautionary statements because defendants sought to include them to challenge the
27 accuracy of the allegations, rather than to demonstrate the warnings existed). In addition, Lead
28 Plaintiff objects to Exhibit 50 to the extent that defendants have highlighted certain language in

1 the summary, which is entirely inappropriate – as even defendants must concede that such
 2 language was not highlighted in the underlying SEC filings or during the analyst conference call
 3 that are supposedly “summarized” in the proposed exhibit.

4 **E. The Authenticity Of Exhibit 2 Is In Question**

5 Defendants represent Exhibit 2 is a “true and correct copy of the transcript of Connetics’
 6 conference call on January 25, 2005.” Declaration of Christopher J. Steskal In Support Of
 7 Defendants’ Motion To Dismiss at 1. However, the authenticity of the transcript is in question.
 8 There is no indication of the source, who transcribed it or if the transcript is even accurate. *See*
 9 *Cooper*, 137 F.3d at 623 (refusing to take judicial notice of a conference call transcript for which
 10 the authenticity and accuracy were disputed). Further, Exhibit 2 differs from the publicly
 11 available “Final Transcript” of the conference call produced by Thomson StreetEvents.
 12 *Compare* Ex. B to Stickney Decl. at p. 9 (attributing statement to defendant Vontz) *with* Ex. 2 at
 13 p. 17-18 (attributing the same statement to defendant Wiggins). Since the authenticity of Exhibit
 14 2 is disputed, judicial notice of Exhibit 2 is inappropriate. *Cooper*, 137 F.3d at 623; *Lee*, 250
 15 F.3d at 688 (judicial notice is appropriate when “authenticity . . . is not contested”).

16 **F. In The Alternative, Defendants’ Motion
 For Dismissal Should Be Converted
 Into Motion For Summary Judgment
 With An Opportunity For Discovery**

17 This matter is governed by the Private Securities Litigation Reform Act (“PSLRA”),
 18 including the automatic stay of discovery during the pendency of the motion to dismiss. 15
 19 U.S.C. § 78u-4(b)(3)(B) (“all discovery and other proceedings shall be stayed during the
 20 pendency of any motion to dismiss, unless the court finds upon the motion of any party that
 21 particularized discovery is necessary to preserve evidence or to prevent undue prejudice to that
 22 party”). As such, Lead Plaintiff has not had the opportunity to obtain discovery. In their motion,
 23 defendants attempt to have it both ways by using the PSLRA discovery stay as a shield while
 24 also attempting to create a one-sided “record” by introducing matters outside the pleadings.
 25

26 Judicial notice of documents not referenced in the Complaint is improper and could
 27
 28

1 convert the motion into one for summary judgment.³ Federal Rule of Civil Procedure 12(d)
 2 provides that, if “matters outside the pleadings are presented to and not excluded by the court,
 3 the motion must be treated as one for summary judgment under Rule 56” and “[a]ll parties must
 4 be given a reasonable opportunity to present all the material that is pertinent to the motion.” Fed.
 5 R. Civ. P. 12(d). Here, defendants attempt to introduce extraneous material outside the
 6 Complaint and not the proper subject for judicial notice. Defendants’ motion, therefore, should
 7 be converted to a motion for summary judgment and Lead Plaintiff should have the opportunity
 8 to obtain discovery for resolution on a developed record.

9 **III. CONCLUSION**

10 The fact remains that the Complaint is a well-pleaded document, with or without judicial
 11 notice of any of the extraneous documents submitted by defendants. Defendants’ attempt to rely
 12 on materials outside of the Complaint to support their motion to dismiss should be rejected.
 13 Accordingly, the Court should deny defendants’ request for judicial notice of Exhibits 2, 49-50
 14 and should not consider Exhibits 6, 7, 8, 10, 12, 13, 30-43, and 48 for the truth of the matters
 15 asserted therein.

16 Dated: June 20, 2008

Respectfully submitted,

17 BERNSTEIN LITOWITZ BERGER
 & GROSSMANN LLP

18 _____
 19 /s/ *David R. Stickney*
 DAVID R. STICKNEY

20
 21 _____
 22 ³ See *U.S. v. Ritchie*, 342 F.3d 903, 907 (9th Cir. 2003) (“When ruling on a Rule 12(b)(6)
 23 motion to dismiss, if a district court considers evidence outside the pleadings, it must normally
 24 convert the 12(b)(6) motion into a Rule 56 motion for summary judgment, and it must give the
 25 nonmoving party an opportunity to respond.”). See, e.g., *Immune Response*, 375 F. Supp. 2d at
 26 995 (striking exhibits to motion for dismissal when “considering these documents as part of the
 27 pleadings at this stage would expand the ‘narrow exception’ and eliminate the distinction
 28 between a motion for summary judgment and a motion to dismiss”); *In re Applied Micro
 Circuits Corp. Sec. Litig.*, Civ. No. 01-cv-0649-K(AJB), 2002 U.S. Dist. LEXIS 22403, at *8
 (S.D. Cal. Oct. 3, 2002) (court not willing to consider “extrinsic evidence” in securities action);
In re NPS Pharm., Inc. Sec. Litig., No. 06-cv-00570, 2007 U.S. Dist. LEXIS 48713, at *6, *9 (D.
 Utah July 3, 2007) (“If, when assessing a Rule 12(b)(6) motion, a court considers matters outside
 the pleadings, the court must treat the motion as a motion for summary judgment under Rule
 56.”).

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CERTIFICATE OF SERVICE

I, Kristina L. Sousek, do hereby certify that on this 20th day of June, 2008, a true and correct copy of the foregoing

LEAD PLAINTIFF'S OPPOSITION TO REQUEST FOR JUDICIAL
NOTICE BY DEFENDANTS CONNETICS CORP., JOHN L. HIGGINS,
LINCOLN KROCHMAL, C. GREGORY VONTZ, AND THOMAS G.
WIGGANS

was filed electronically. Those attorneys who are registered with the Electronic Case Filing ("ECF") System may access this filing through the Court's system, and notice of this filing will be sent to the parties by operation of the Court's ECF System. Attorneys not registered with the Court's ECF system will be duly and properly served via Federal Express or U.S. Mail (as indicated on the attached Service List), in accordance with the Federal Rules of Civil Procedure and the Court's Local Rules.

I further declare that, pursuant to Civil L.R. 23-2, on this date I served copies of the above documents on the Securities Class Action Clearinghouse by electronic mail through the following electronic mail address provided by the Securities Class Action Clearinghouse:

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/s/Kristina L. Sousek

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